



[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-Day Comment Request Extension to May 31, 2016

Study to Estimate Radiation Doses and Cancer Risks from Radioactive Fallout from the Trinity Nuclear Test - National Cancer Institute (NCI)

SUMMARY: In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Cancer Institute, the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection

techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: Steve Simon, Dosimetry Unit Head and Staff Scientist, Radiation Epidemiology Branch, Division of Cancer Epidemiology & Genetics, National Cancer Institute, NIH, 9609 Medical Center Drive, MSC9778, Bethesda, MD 20892-9778 or call non-toll-free number (240)-276-7371 or E-mail your request, including your address to: ssimon@mail.nih.gov. Formal requests for additional plans and instruments must be requested in writing.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received by May 31, 2016.

PROPOSED COLLECTION: Study to Estimate Radiation Doses and Cancer Risks from Radioactive Fallout from the Trinity Nuclear Test, 0925-NEW, New, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This research plan is for a radiation-related cancer risk projection study for the residents of the state of New Mexico (NM) potentially exposed to radioactive fallout from the Trinity nuclear test conducted in 1945. Data will be collected on diet and lifestyle from three groups in NM (non-Hispanic white, Hispanic, and Native American) alive in the 1940s via focus groups and key informant interviews and will be used to derive means and ranges of exposure-related parameters, such as consumption of contaminated foodstuffs, collection and use of water, time spend

outdoors, and building materials. These parameter values will be used with historical fallout deposition data in fallout dose assessment models to estimate external and internal radiation doses to typical persons in all counties in New Mexico by ethnicity and age. The estimated doses will be used with literature-derived risk and parameter values on risk/unit dose to project the excess cancers expected (per 1,000 persons within each stratum) including uncertainty on each estimate. Endpoints are leukemia, thyroid cancer, stomach cancer, colon cancer, and all solid cancers combined.

This data collection is needed to accomplish the overall Trinity Study goals, which are to: 1) estimate external and internal radiation dose to the four primary organs/tissues of interest (thyroid, stomach, colon, and red bone marrow) from primary radionuclides in nuclear testing fallout in each county of New Mexico as a result of the Trinity test, stratified by age, gender, ethnicity, and conditions of exposure (low, medium, high); 2) in each county, estimate the number of excess cancer cases to organs of interest per 1,000 (hypothetical) persons stratified by age, gender, ethnicity, and conditions of exposure (low, medium, high).

The study data will be collected via focus group and individual interview. Between 10 and 15 focus groups with up to 8 participants are planned. These participants will be 70 years old and older, living in New Mexico, who were alive at the time of the Trinity nuclear test and living in any of 19 Native American pueblos/tribes or Hispanic/Latino and non-Hispanic white communities in or near the fallout region in New Mexico. Additionally, up to 30 individual interviews are planned with key informants chosen to represent a variety of experiences and expertise. Individuals who prefer not to take part in a focus group will be interviewed individually as key

informants. The investigators will collaborate with community representatives who will recommend potential participants for either the focus groups or interviews.

The objective of the focus groups and interviews is to collect information directly from community members who were alive at the time of the Trinity test, or with direct knowledge of specific life circumstances, cultural patterns, and dietary practices of Native Americans, Hispanics/Latinos, or non-Hispanic whites living in New Mexico at this time. In this study, two interviewers, including one with extensive experience working with tribal communities, will moderate the focus groups and conduct in-depth interviews. Translators and interpreters with experience in the study populations will be presented when needed. Each focus group and interview will be scheduled for no more than two hours and will take place in office settings, community facilities, or municipal facilities.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 395.

Estimated Annualized Burden Hours

Type of Respondents	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (in hours)	Annual Burden Hours
Individuals	Screeners	300	1	10/60	50
	Consent Form	150	1	10/60	25
	Focus Groups	120	1	120/60	240
	Pre-Focus Group Guide	120	1	10/60	20
	Key Informants and Academics Interview	30	1	120/60	60
Totals		300	720		395

Dated: May 6, 2016.

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